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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,431	01/12/2001	Kirsten L. Valley	047-D1-C1	1426

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EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 10/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary

Application No.

09/759,431

Applicant(s)

VALLEY ET AL.

Examiner

Cris L. Rodriguez

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species s) figures 37-41, claims 1-6, and 8-12 in Paper No. 7 is acknowledged.
2. Claims 7 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7.
3. Please note that the Examiner has withdrawn claims 7 and 13 from consideration as being drawn to a non-elected species.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

- (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
- (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1, 5, 6, 8, 9, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Abele et al (US 5,693,014).

Abele discloses a balloon catheter (figs. 7, and 9-12) having a balloon with low and high friction portions, and a method for anchoring the catheter as claimed. The high friction portion retains the catheter in position within the vessel during inflation. The catheter includes a first (guidewire) lumen open at its distal end, and a guidewire. Abele also

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discloses that the balloon can be inflated either through a first (guidewire) lumen or an auxiliary lumen (not shown, col. 4 lines 1-7) as well known in the art.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 2-4, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abele et al in view of Booth et al (US 5,653,690).

Abele discloses the invention substantially as claimed. However, Abele fails to disclose the step of the balloon being positioned in the ascending aorta, and the step of delivering cardioplegic fluid through the first (guidewire) lumen.

Booth teaches a balloon catheter for delivering cardioplegic fluid into the heart and arresting the heart. (Figs. 1, 4, 5) with retention means 46 to securely hold the catheter in place during inflation. Booth also recognizes that the cardioplegic fluid can be delivered in an antegrade or retrograde manner (col. 1 lines 23-40). The catheter has an infusion (first) lumen 13, an inflation lumen 32 (auxiliary lumen), and a stylet 102 (guidewire) to direct the catheter into the heart. The balloon retention means 46 permit the balloon to fold into an accordion fold (fig 5) when not inflated, and provides securely and effective seal when inflated (col. 7 lines 12-27). Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to deliver cardioplegic fluid with Abele's catheter, since Booth suggest that cardioplegic fluid can be delivered through the

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first (guidewire) lumen in a balloon catheter having retaining means as well. Furthermore, since Booth's recognizes that cardioplegia may be administered in an antegrade or retrograde manner (col. 1 lines 23-40), it would have been obvious to one of ordinary skill in the art, having knowledge of its method of anchoring a balloon catheter and delivering cardioplegic fluid in certain part of the heart, to use the same method and treat a different location in the heart in order to arrest the heart.

Conclusion


8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vigil ('234 and '634), Liprie, Wang et al, Lane et al, Euteneuer, Deuss, Davey, Houser, and Smith.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

October 16, 2002


Cris L. Rodriguez
Examiner
Art Unit 3763


MICHAEL J. HAYES
PRIMARY EXAMINER